

CLAIMS

1. A medicinal aerosol steroid solution formulation product with enhanced chemical
5 stability, including:
an aerosol container equipped with a dispensing valve and containing a
medicinal aerosol formulation having a 20-ketosteroid drug dissolved therein;
said 20-ketosteroid having an OH group at the C-17 or C-21 position or
both, provided that said 20-ketosteroid is other than flunisolide; and
10 wherein said container is provided with a non-metal interior surface so as to
reduce chemical degradation of the 20-ketosteroid.
2. The product of claim 1, wherein said container is made of aluminum having an
inert interior coating.
- 15 3. The product of claim 2, wherein the interior coating is an epoxy-phenolic lacquer.
4. The product of claim 1, wherein said dispensing valve is a metered dose valve.
- 20 5. The product of claim 1, wherein said medicinal aerosol formulation includes a
hydrogen-containing propellant.
6. The product of claim 5, wherein the hydrogen-containing propellant is a
hydrofluorocarbon.
- 25 7. The product of claim 6, wherein the hydrofluorocarbon propellant is selected from
the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane,
and mixtures thereof.
- 30 8. The product of claim 1, wherein said medicinal aerosol formulation includes
ethanol.

9. The product of claim 1, wherein said 20-ketosteroid has an OH group at the C-17 position, but not at the C-21 position.
10. The product of claim 1, wherein said 20-ketosteroid has an OH group at the C-21 position, but not at the C-17 position.
11. The product of claim 1, wherein said 20-ketosteroid has an OH group at both the C-17 and C-21 positions.
12. The product of claim 1, wherein the 20-ketosteroid is a corticosteroid selected from the group consisting of budesonide, triamcinolone acetonide, desonide, flucinolone acetonide, alclometasone, beclomethasone, beclomethasone 17-monopropionate, betamethasone, betamethasone 17-valerate, clocortolone, desoximetasone, dexamethasone, dexamethasone sodium phosphate, dexamethasone 21-isonicotinate, diflorasone, flumethasone, methylprednisolone, paramethasone, prednisolone, triamcinolone, clobetasol, and fluorometholone.
13. The product of claim 1, wherein the 20-ketosteroid is budesonide.
14. The product of claim 1, wherein the 20-ketosteroid is triamcinolone acetonide.
15. The product of claim 1, wherein the 20-ketosteroid is dexamethasone.
16. The product of claim 1, wherein the 20-ketosteroid is betamethasone 17-valerate.
17. The product of any preceeding claim wherein the container and/or the valve has a coating applied by vapor deposition.
18. The product of claim 17, wherein metal valve components have a coating applied by vapor deposition.
19. The product of claims 17 or 18, wherein the coating is a glass.

20. The product of claim 19, wherein the coating is applied by the Silcosteel process.
- 5 21. A method of reducing the chemical degradation of a medicinal 20-ketosteroid dissolved in a formulation contained in a metal container, said 20-ketosteroid being other than flunisolide and having an OH group at the C-17 position or C-21 position or both, comprising the step of providing a coating of inert material on the interior surface of the metal container so as to reduce reaction of the 20-ketosteroid with metal oxides from the container.
- 10 22. A process for making a chemically stable steroid solution aerosol product by filling into a container an aerosol formulation comprising a dissolved 20-ketosteroid other than flunisolide, said 20-ketosteroid having an OH group at the C-17 position or C-21 position or both, and said container having an inert non-metal interior surface so as to avoid chemical degradation of the 20-ketosteroid due to interaction with the
- 15 container.
23. An aerosol valve having a non-metal coating applied to one or more metal surfaces by vapor deposition.
- 20 24. The valve of claim 23 wherein the coating is fused silica.
- 25 25. A medicinal aerosol product equipped with a metering valve and containing a medicinal aerosol formulation, said product comprising a layer of fused silica material applied on an internal surface of said product in contact with the formulation.
- 30 26. The product of claim 25, wherein said layer is on at least one component of the metering valve.
27. The product of claim 25, wherein said layer is sub-micron in thickness.

28. A method of making an improved metered dose medicinal aerosol product containing a medicinal aerosol formulation, comprising the step of coating an internal surface of said product, that is to be in contact with the formulation, with a layer of fused silica.

5